K062906

NOV 17 2006

XI. 510(k) Summary

Submitter: Mr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16030 Avegno (GE), Italy. Phone: 39 0185 7885 880.

I. Classification Name and Number: Material, Tooth Shade, resin (EBF 872.3690)

II. Common/Usual Name: Dental Dental Composite for direct and indirect restoration.

III. Proprietary Name: ENA HFO, ENA Tender, ENA Flow,.

IV. Registration No.: Foreign, in process

V. "ISO 4049:2000 Dentistry – Polymer – Based Filling, Restorative and Luting materials".

VI. Premarket Notification truthful and accurate statement

VII. Description of the Device: ENA HFO is a system for direct and indirect aesthetic restorations in anterior and posterior sectors, composed by a light curing radiopaque composite, available in different colors, with accessories for application and polishing. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally.

VIII. Labels and Labeling: Draft labels of the ENA HFO system and instructions for use are provided.

IX. Substantial Equivalence: The the ENA HFO system is substantially equivalent to several other composite systems currently on the market used for direct and indirect restorations by dentist and dental technicians. A list of these is provided.

1. These products have the same intended use as predicate devices, intended to be used as direct or indirect teeth restoration material.

2. The technological characteristics for this product are similar to those of the predicate devices and those currently on the market. They have similar composition (bis-GMA resin and glass filler) and similar physical data.

IX.1 Risk to Health

Potential adverse affects and complications common to composite materials include:
- Allergies or hypersensitivities
- No or not complete adhesion on teeth
- Wrong or not complete curing
- Polymerisation gap, shrinkage

- Wrong or not complete filling of the cavity

cytotoxicity tests appears in appendix V.1

X. Indications for Use. ENA HFO is a composite system for direct and indirect aesthetic restorations in anterior and posterior sectors.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eugenio Miceli
QA Manager
Micerium, SpA
Via Marconi 83
16030 Avegno (Ge)
ITALY

NOV 17 2006

Re: K062906
Trade/Device Name: ENA HFO Composite System
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 19, 2006
Received: September 27, 2006

Dear Mr. Miceli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

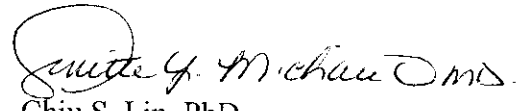
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062906

Device Name: ENA HFO Composite System

Indications for Use:

ENA HFO is a composite system for direct and indirect aesthetic restorations in anterior and posterior sectors.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K062906